Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Otex Ear Drops Solution 5 %w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea Hydrogen Peroxide 5.0% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Ear drops, solution
Clear, straw, coloured viscous ear drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an aid in the removal of hardened wax.

4.2 Posology and method of administration

For adults (including the elderly) and children:

Instill up to 5 drops into the ear. Retain drops in ear for several minutes by keeping the head tilted and then wipe away any surplus.

Repeat once or twice daily for at least 3 to 4 days, or as directed by the physician.

4.3 Contraindications

Do not use if the eardrum is known or suspected to be damaged, in cases of dizziness, or if there is any other ear disorder (such as pain, discharge, inflammation, infection or tinnitus).

Do not use after syringing or after ill-advised attempts to dislodge wax using fingernails, cotton buds or similar implements, as such mechanical efforts can cause the ear's delicate inner lining to become damaged, inflamed or infected, whereupon the use of ear drops can be painful.

Do not use where there is a history of ear problems, unless instructed to do so by a doctor.

Do not use if sensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Keep Otex away from the eyes.
As with all medicines, keep out of the reach of children.
For external use only.
Replace cap after use, and return bottle to carton.

4.5 Interaction with other medicinal products and other forms of interaction

Otex should not be used at the same time as any other type of topical preparation in the ear.

4.6 Pregnancy and lactation

No known side effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Due to the release of oxygen, patients may experience a mild, temporary effervescence in the ear.
Stop usage if irritation or pain occurs.
Instillation of ear drops can aggravate the painful symptoms of excessive ear wax, including some loss of hearing, dizziness and tinnitus. Very rarely, blurred vision and unpleasant taste have been reported. If patients encounter any of these problems, or if their symptoms persist or worsen, they should discontinue treatment and consult a doctor.

4.9 Overdose

No adverse effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

After insertion of the drops into the ear, the urea hydrogen peroxide complex liberates oxygen which acts to break up the hardened wax. The hydrogen peroxide component is also a cerumenolytic. Its action as an antiseptic, especially in sites with relative anaerobiosis, is well known. The glycerol and urea assist in softening the wax, so that it may more easily be removed from the ear, either with or without syringing. The urea acts as a mild keratolytic, helping to reduce the keratin-load in the wax debris, thereby assisting penetration of the other components.

5.2 Pharmacokinetic properties

Otex is intended only for the treatment of impacted wax in the *external* auditory canal. The ingredients of the formulation are therefore readily available for intimate contact with the affected area, as the drops are instilled into the ear and retained therein for several minutes by tilting the head.

5.3 Preclinical safety data

The preclinical safety profile of this preparation has been superseded by many years of widespread clinical usage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

8-Hydroxyquinoline
Glycerol

6.2 Incompatibilities

Do not use concurrently with anything else in the ear.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Store upright. Do not store above 25°C.
Replace cap after use and return bottle to carton.

6.5 Nature and contents of container

8-12 ml BOTTLES comprising either:

a. amber glass incorporating a specially designed polythene pipette APPLICATOR enclosed in a polypropylene SCREW CAP.
b. low density polyethylene, with low density polyethylene nozzle APPLICATOR and tamper-evident SCREW CAP.

Supplied as original packs (OP).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
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8 MARKETING AUTHORISATION NUMBER

PA 727/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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